

3D/Saline infusion Sono-hysterography versus conventional office hysteroscopy in uterine cavity evaluation prior to ICSI procedure

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Abstract

Objective: To assess the predictive values of 3D Saline infusion sono-hysterography (SIS) in assessment of uterine cavity abnormalities or lesions in comparison to conventional office hysteroscopy (OH) prior to ICSI procedure.

Study design: A prospective observational study.

Setting: Obstetrics and Gynecology Department, faculty of medicine, south Valley University, Egypt.

Duration: From April 2017 to March 2018.

Patients and methods: This study was conducted on 88 infertile women from the attendants for infertility clinic and underwent ICSI procedure. Uterine cavity had been evaluated using 3D/SIS by taking multiple transverse views in distended uterine cavity, few days later OH was done. The two procedures were done by 2 different investigators and the findings were recorded separately.

Results: There was no a statistically significant difference between 3D/SIS and OH in the findings during uterine cavity evaluation with p value > 0.05. Sensitivity, specificity, positive, negative predictive values and diagnostic accuracy of 3D/SIS in assessment of uterine cavity lesions and anomalies were (64.4%, 94.3%, 73.4%, 91.7%, and 88.6% respectively). As regarding to pain score according to visual analog scale (VAS), there was a high statistically significant difference between OH and 3D/SIS with p-value <0.01.

Conclusions & recommendations: 3D/SIS is considered a reliable, accurate and relatively safe procedure for uterine cavity abnormalities diagnosis and can be used as an alternative method for detection of uterine cavity abnormalities and any lesions prior to ICSI procedure.

Introduction

Intracytoplasmic sperm injection success rate required good evaluation of both couples, uterine cavity evaluation for any abnormalities or pathological lesions plays an important role in enhancement of implantation rate and squally increased ICSI results [1-3]. Uterine cavity abnormalities represent the actual factor of infertility in 10% to 15% of infertile couples.

Anyway, uterine cavity abnormalities have been found in 34% to 62% of infertile females [4]. Diagnostic hysteroscopy has been considered as the gold standard tool for uterine cavity pathologies and uterine malformations assessment [5]. In a systematic review and meta-analysis of 2 randomized and 3 non-randomized control trials on about 1691 infertile women had concluded that hysteroscopic evaluation prior to a subsequent IVF or ICSI attempts statistically significantly enhancement of the odds ratio for pregnancy rate in cases with at least previous 2 failed IVF or ICSI trials [6].

Three-dimensional (3D) ultrasound has become an integral part of the gynecological assessment [7]. Many methods as hysterosalpingography, trans-vaginal sonography, 3D trans-vaginal sonography, 3D saline sono-hysterography (SIS) and office hysteroscopy

(OH), could be used in the assessment of uterine anomalies and lesions. OH had been established as the gold standard in female infertility work up with its high accuracy in diagnosis of uterine cavity pathology and abnormalities [8-10]. Transvaginal 3D ultrasonography recently had the capability of accuracy and represents as non-invasive examination tool for uterine cavity evaluation as in outpatients. Therefore, it could take place the OH particularly as regarding to its low cost if compared with hysteroscopy beside no serious side effects or complications [11].

SIS represents a procedure where isotonic saline (NaCl 0.9%) can be instilled into the uterine cavity through cervical canal to provide enhancement of good visualization of the endometrial lining during TVUS examination. Also, gel Infusion sono-hysterography can be used

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Key words: 3D Saline infusion sono-hysterography, Office hysteroscopy, ICSI

Received: October 05, 2018; **Accepted:** October 15, 2018; **Published:** October 19, 2018

as SIS, both of them are safe, simple, can be tolerated well and have good accuracy in diagnosis of intra-uterine abnormalities [12].

The aim of this study was to assess the predictive values of 3D/SIS in assessment of uterine cavity abnormalities or lesions in comparison to OH prior to ICSI procedure.

Patients and methods

This was a prospective observational study conducted on 88 infertile women from the attendants for infertility clinic of obstetrics and gynecology department of Qena university hospital underwent ICSI procedure at assisted reproductive unit from April 2017 to March 2018.

Inclusion criteria were; (1) Age>40 years (2) body mass index <30 kg/m² (3) duration of infertility < 10 years. Exclusion criteria were; (1) chronic or current pelvic inflammatory disease (2) Cervical infection or lesions as fibroid (3) Undiagnosed uterine bleeding. A written consent was taken from every patient accepted to participate in this study.

Thorough history was taken, general and local examination was done for all participants in this study. Uterine cavity was assessed by 3D/SIS. Few days later OH was done. The two procedures were done in early proliferative phase of menstrual cycle day by 2 different operators and the findings were recorded separately. Broad spectrum antibiotic was given prophylactically to all cases.

Technique

(1) 3D/SIS: Cusco’s speculum was used for visualization of the cervix; the cervix was cleansed with a povidone-iodine 10%. Intrauterine insemination catheter had been used for saline instillation to uterine cavity, the catheter was connected to a syringe (50 cc) filled with saline, a tenaculum was used for gentle traction of the cervix. Vaginal speculum had been removed and a transvaginal transducer was introduced into the vagina, the uterus was determined in the cross-sectional plane. 50 ml of sterile warmed saline (37°C) was instilled.

Instillation into the uterine cavity was done through pushing the of the syringe plunger with slow and light pressure by the assistant. The uterine cavity contour had been inspected for any irregularity and any suspicious lesions inside the cavity. Endometrial lining deformities and appearance of any structures with or without well-defined outlines or presence of variable echogenicity had been recorded as abnormal findings. The US apparatus used in this study was a Sonoace X8, Medison ultrasound system (seoul, Korea) equipped with a 6–12 MHz 3D transvaginal probe. Images were taken in the midsagittal section.

(2) Office Hysteroscopy was performed with a rigid microhysteroscope (Karl Storz, Germany) with a 2.9 mm diagnostic sheath. A hysteroscopic camera of Karl Storz Germany fitted to the eye piece of the optic sheath where it is transmitted to a monitor with video recording is the way of documentation of the hysteroscopic findings. Normal Na Cl 0.9 solutions were used as distention medium with a maximum pressure of 100 mm Hg was allowed. The whole uterine cavity had been inspected beside inspection the tubal ostia.

Vaginoscopy was the main trend used before office hysteroscopy. Anterior, posterior and lateral walls of uterine cavity were carefully assessed for any intrauterine abnormalities e.g. uterine septum or polyps, adhesions and submucous fibroids. 100 mm visual analog scale (VAS) was used for pain detection that experienced by the patients

during the above 2 procedures Sensitivity, specificity, positive and negative predictive values of 3D/SIS in detection of uterine anomalies or intrauterine lesions were assessed and data was collected for further statistically analyzed.

Statistical methods

The data was collected and entered on Microsoft access database and analyzed using the Statistical Package for Social Science (SPSS Inc., Chicago, version 19). Qualitative variables were expressed as percentages and compared by Fisher’s exact test. Level of significance “P” value was evaluated, if P value<0.05 was considered significant.

Results

The mean women age was 28.28 years, the mean BMI was 26.07 kg/m² and 92.1% had complained of infertility (1ry=51.2% and 2ry=40.9%) while only 7.9 % complained of recurrent abortion (Table 1).

There was no a statistically significant difference between 3D/SIS and OH in the findings during uterine cavity evaluation with p value > 0.05 (Table 2).

Sensitivity, specificity, positive, negative predictive values and diagnostic accuracy of 3D/SIS in assessment of uterine cavity lesions and anomalies were (64.4%, 94.3%, 73.4%, 91.7%, 88.6% respectively) (Table 3).

As regarding to pain score according to visual analog scale (VAS), there was a high statistically significant difference between 3D/SIS and OH with p-value <0.01 (Table 4).

Table 1. Patient characteristics

Age (years) n (%)	
<25	25 (28.4)
25 - 30	37 (42.1)
>30	26 (29.5)
Mean ± SD (Range)	28.28 ± 5.16
BMI (kg/m ²) n (%)	
<25	61 (69.32)
≥25	27 (30.68)
Mean ± SD (Range)	26.07 ± 2.09
Patient complaint n (%)	
Infertility	
Primary	45 (51.2)
Secondary	36 (40.9)
Recurrent abortion	7 (7.9)

Table 2. Incidence of uterine cavity abnormalities with 3D/SIS and OH

	3D/SIS	OH	P-value
	NO (%)	NO (%)	
Normal findings	73 (82.9)	71 (80.7)	0.082
Abnormal findings	15(17.1)	17 (19.3)	
Endometrial polyp	8 (9.1%)	11 (12.5)	
Submucous fibroid	3 (3.4%)	3 (3.4)	
Septate uterus	2 (2.3%)	2 (2.3)	
Bicornuate uterus	2 (2.3%)	1 (1.1)	

Table 3. Sensitivity, specificity, positive and negative predictive values of 3D/SIS in assessment of uterine cavity lesions and anomalies

Sensitivity	Specificity	+ve PP	-ve PP	Accuracy
64.4% (11/17)	94.3% (67/71)	73.4% (11/15)	91.7% (67/73)	88.6% (78/88)

Table 4. Sensitivity, specificity, positive and negative predictive values of 3D/SIS of variable uterine cavity lesions and anomalies

	Sensitivity	Specificity	+ve PP	-ve PP	Accuracy
Endometrial polyp	63.60%	98.70%	87.50%	95%	94.30%
	(7/11)	(76/77)	(7/8)	(76/80)	(83/88)
Submucous fibroid	100%	100%	100%	100%	100%
	(3/3)	(85/85)	(3/3)	(85/85)	(88/88)
Septate uterus	50%	98.80%	50%	98.80%	96.60%
	(1/2)	(84/85)	(1/2)	(84/85)	(85/88)
Bicornuate uterus	100%	98.80%	50%	100%	98.80%
	(1/1)	(86/87)	(1/2)	(86/86)	(87/88)

Discussion

The congenital and acquired abnormalities of uterus are considered major causes of women infertility so evaluation of the uterine cavity should be in mind during work up of infertility particularly in unexplained one [13]. Numerous tools and procedures have been used in diagnosis of intrauterine lesions, the more frequently have been used, TVUS, SIS, diagnostic or OH, and endometrial biopsy). They can be used individually or in combination, the choice of the test depends on its highest diagnostic accuracy [14].

Although SIS has been reported in enhancement and augmentation of the endometrial cavity imaging, diagnostic hysteroscopy is still universally accepted as a gold standard for uterine cavity evaluation in spite of it is invasive technique and its association with patients discomfort and sometimes leads to vasovagal syncope [15].

In this study the abnormal findings were almost the same that was reported by Kasius *et al.* [16], who had found endometrial polyps were the most frequent pathology of uterine cavities during the assessment, followed by the other lesions and anomalies. The same results had been reported by Fatemi *et al.* [17] who had found in 678 asymptomatic infertile women undergoing assisted reproduction techniques, the endometrial polyps and submucous fibroids had the highest prevalence of unsuspected hidden intrauterine abnormalities.

The role of endometrial polyps on decline fertility rate is not fully understood, but some studies had shown that improvement in pregnancy rates had occurred after polypectomy [18]. In our study new technique was introduced during SIS using 3DUS, where the uterine cavity was assessed in cross sections in multiple levels by sliding movement of transvaginal probe that could be had better imaging for the uterine cavity. In our study the sensitivity of 3D/SIS in comparison with OH (as the gold standard) was high in submucous fibroid and bicornuate uterus (100% for both), Specificity was high in submucous fibroid 100% and > 98% for other abnormalities.

Positive predictive value was high in submucous fibroid and endometrial polyps (100% and 98.7% respectively). The negative predictive value was high in submucous fibroid and bicornuate (100% for both) and 98.8% for septate uterus. The diagnostic accuracy was high in submucous fibroid and bicornuate uterus (100% and 98.8% respectively), these results agreed with many previous studies reports as El-Sattar MA *et al.* [19] and Mohamed *et al.* [20].

Gunes and associates [21] had studied the accuracy of SIS in 83 women had abnormal uterine bleeding with suspicion of endometrial cavity abnormalities, they had concluded that the reliability and the accuracy of SIS for detection of uterine cavity abnormalities and lesions was high and it could be a good reliable method alternative to hysteroscopy in detection of uterine cavity abnormalities.

In this study accuracy of 3D/SIS in diagnosis of intrauterine lesions or uterine abnormalities was high and can be sufficient and

not need for further hysteroscopy particularly for its low incidence of complications and had low of patient compliance as regarding to pain experience during procedure and these results agreed with what reported by Grimbizis *et al.* [22] who had considered that hysteroscopy was used only as a complementary procedure when abnormal findings diagnosed by the other methods as hysterosalpingography (HSG) and US [23,24]. Also, 3D/SIS had an advantage over detection of uterine cavity abnormalities it can detect lesions in the uterine wall (e.g. interstitial fibroid and adenomyosis) and adnexa (tube and ovary) where conventional hysteroscopy unable to do so.

Conclusions and recommendation

3D/SIS is considered a reliable, accurate and relatively safe procedure for uterine cavity abnormalities diagnosis and can be used as an alternative method for detection of uterine cavity abnormalities and any lesions prior to ICSI procedure.

Conflict of interest

The authors declare that they have no conflict of interest.

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